

UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

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EMERY DODD AND ELEN DODD; ROBERT DODD;
MARY DOMINGUEZ AND FRANK DOMINGUEZ;
VIVIAN DOMINGUEZ AND RAYMOND
DOMINAGUEZ; MARIE DOPKINS AND RUSSELL
H. DOPKINS; JOHN DRENNAN AND SHIRLEY
DRENNAN; BARBARA DROBICK AND KENNETH
DROBICK; PAULINE DUERKOP AND GERALD
DUERKOP; JOHNNY DUNCAN AND LEE ANNA
DUNCAN; FRANCIS DYKSTRA; THEODORE
EICHENLAUB AND THELMA EICHENLAUB;
EDNA ELLIS; RONALD ELLIS AND BARI ELLIS;
LEWIS ELLSWORTH AND PENNY ELLSWORTH;
JOHN ENGSTROM AND CAROL ENGSTROM;
CAROL ESTRADA AND MARY HELEN ESTRADA;
JOHN FARRELL AND LENORE FARRELL; EDWARD
FELIX AND LOUISE FELIX; SCOTT FERGUSON;
HERBERT FINE AND LOUISE FINE; ROBERT
FINKLE; ROBERT FISCHER; GLENN FLATT;
NANCY FOGLMAN AND JAMES FOGLMAN;
PETER FOLEY; GARY FORD AND MARY H. FORD;
ANNA FRANCE AND ROBERT FRANCE; LOUISE
GAGNON; WILLIAM GALBRAITH AND GWEN
GALBRAITH; JOE GALLEGOS AND OFELIA
GALLEGOS; PAUL GARRAHAN; SUSAN
GEISSENBERGER; DORIS GEZZAR; REX GIBBS
AND VIOLET D. GIBBS; EUGENIA GLASCO AND
JOE N. GLASCO; GAIL GODDARD; EARL GOLDMANN;
EARL GOLDSTEIN AND MELVIN GOLDSTEIN;
BARBARA GOLMON AND LLOYD D. GOLMON;
LEOPOLDO GOMEZ AND LYDIA T. GOMEZ; RUBY
GONZALES AND JOHN L. GONZALES; HELEN
GRACIA AND EDWARD GRACIA; MARY GRANISON
AND WILLIAM GRANISON; KATES GRAVES;
FREDERICK GREEN AND CLARA GREEN; SADY
GREER AND HAROLD E. GREER; KENNETH
GREGGORY AND NANCY GREGGORY; JOHN
GRGAT AND MARGARET GRGAT; CHRISTA GROSS
AND ALFRED GROSS; GERALD GROVEN AND
PATI GROVEN; BOBBY GUYTON AND SATNSILAVA
GUYTON; MARY HABRE; DONALD HALL AND PATSY
HALL; JACQUES HANDFIELD; HARVEY HARDEN

(Pending Transfer to
In re Baycol Products Litig.
MDL No. 1431 [D. Minn.])

2003 - CV-9711 (J. Sweet)

**DEFENDANT BAYER
AG'S ANSWER
AND DEFENSES**

AND IRMA HARDEN; JJESS HARDY AND MARLENE HARDY; VICTOR HARILDSTAD AND GENEVA HARILSTAD; RITA HARLEV AND ROBERTA JEAN HARLEV; CATHERINE HARTLINE AND MICHAEL HARTLINE; RONALD HARUFF AND PATSY HARUFF; BARBARA HAVENS AND JACK HAVENS; LUPE HAVILAND AND DALE HAVILAND; ALDEN HERMAN AND ELIES HERMAN; ROBERT HERNANDEZ; MARIA HERRERA AND VICTOR HERRERA; VICTOR HERRERA AND MARIA HERRERA; FLORENCE HERTAUS; TONY HIGHT AND ANN M. HIGHT; ROBERT HILDEBRANDT AND SHARON HILDEBRANDT; RALPH HINOJOSA, JR. AND LINDA HINOJOSA, JR.; JOHN HOBAN AND LOLA HOBAN; GLEN HOCH AND LOIS HOCH; LAWRENCE HIEL, JR. AND DEBORAH HOEL; BENITA HOFFMAN AND CHARLES HOFFMAN; THEODORE HOLLIDAY AND COLLEEN HOLLIDAY; MARJORIE HOMER AND JOHN HOMER; DESMOND HOOEY AND GRACE HOOEY; JERALD HORTON AND JOYCE HORTON; HARIETTA HOWARD AND JERALD HOWARD; GLORIA HOWSON; RICHARD HUEBNER AND SUSAN HUEBNER; MAE HUGGINS AND ARCHIE HUGGINS; MYRNA HUNT; PAUL HUPP AND MARAJEAN HUPP; BONNIE HYMAN-FIGY AND EUGENE HYMAN; CALVIN JACKSON AND FLOY JACKSON; ROBERTA JACKSON; JOHN JACKSON, JR. AND SHELBY JACKSON; FRANCISCO JAIME; ROSALIE JAMESON; PATRICIA JANSSEN AND JOHN JANSSEN; JANICE JERNIGAN; GERALD JIRON; DALCIE JOHNSON; EDWARD JOHNSON AND SHIRLEY JOHNSON; FLOYD JOHNSON AND GILLIAN GRAFTON; JERI-LOU JOHNSON AND JOSEPH JOHNSON; MARVIN JOHNSON AND DORIS JOHNSON; RICHARD JONASON AND BESS M. JONASON; GAIL JONES; NANCY JONES AND ALBERT JONES; MIDA JORDAN; ALEX JUAREZ AND NANCY JUAREZ; JERRY KAMCHI AND BEVERLY KAMCHI; DENNIS KELLEY AND SHERRY KELLEY; WILLIAM KELLEY AND BARBARA KELLEY;

Plaintiffs,

-against-

BAYER CORPORATION,

BAYER AG,
GLAXOSMITHKLINE, PLC,
SMITHKLINE BEECHAM CORPORATION,
D/B/A GLAXOSMITHKLINE,

Defendants.

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Defendant BAYER AG answers the First Amended Verified Complaint (“Complaint”) in this action as follows:

1. Bayer AG is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 1. Nevertheless, Bayer AG denies that the Plaintiffs named herein are properly joined and explicitly reserves all rights associated therewith including the right to move to sever Plaintiffs’ claims.

2. a. Bayer AG admits that Bayer Corporation is an Indiana corporation and that Bayer Corporation’s principal place of business is located at 100 Bayer Road, Pittsburgh, Pennsylvania. Bayer AG further admits that, at all times relevant to this action, Bayer Corporation had facilities in the State of New York. Because of the vagueness and ambiguity of the remaining allegations in paragraph 2a, Bayer AG is without knowledge or information sufficient to form a belief as to the truth of those allegations. For a further response, Bayer AG states that to the extent that the Complaint contains allegations that are directed to Bayer Corporation by use of the term “defendants” or otherwise, no answer is required by Bayer AG, and Bayer AG therefore makes no response in this Answer to the allegations that are directed to Bayer Corporation.

 b. Bayer AG admits that Bayer AG is a German corporation. Bayer AG denies that Bayer AG has a principal place of business in the United States and in Pennsylvania. Bayer AG denies the remaining allegations in paragraph 2b. Bayer AG further states that Bayer

AG does not contest specific personal jurisdiction over Bayer AG in this action, but Bayer AG denies that general jurisdiction exists over Bayer AG in this action.

c. Bayer AG admits, on information and belief, that GlaxoSmithKline plc is an English public limited company with its principal place of business in England. Bayer AG is without knowledge or information sufficient to form a belief as to the truth of the remaining allegations in paragraph 2c.

d. Bayer AG admits, on information and belief, that SmithKline Beecham Corporation d/b/a GlaxoSmithKline is a Pennsylvania corporation with its principal place of business in Pennsylvania. Bayer AG is without knowledge or information sufficient to form a belief as to the truth of the remaining allegations in paragraph 2d.

3. Bayer AG denies the allegations in paragraph 3.

4. Bayer AG admits that Bayer Corporation is a wholly owned subsidiary of Bayer AG. Bayer AG denies any remaining allegations in paragraph 4.

5. Because of the vagueness and ambiguity of the allegations in paragraph 5, Bayer AG is without knowledge or information sufficient to form a belief as to the truth of those allegations.

6. Bayer AG is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 6.

7. Bayer AG admits that cerivastatin sodium, a prescription medication, was sold under the trade name Baycol® in the United States and the trade name Lipobay® in certain countries outside of the United States. Bayer AG denies the remaining allegations in paragraph 7.

8. Bayer AG admits that cerivastatin sodium, which was sold in the United States under the trade name Baycol®, was manufactured in Germany. Bayer AG denies any remaining allegations in paragraph 8.

9. Bayer AG admits that prior to August 8, 2001, Bayer AG manufactured cerivastatin sodium in Germany and Bayer Corporation sold cerivastatin sodium under the trade name Baycol® in the United States. Because of the vagueness and ambiguity of the remaining allegations in paragraph 9, Bayer AG is without knowledge or information sufficient to form a belief as to the truth of such allegations.

10. Bayer AG denies that Baycol® is a registered trademark of GW USA, Inc. Bayer AG is without knowledge or information sufficient to form a belief as to the truth of the remaining allegations in paragraph 10.

11. Because of the vagueness and ambiguity of the allegations in paragraph 11, Bayer AG is without knowledge or information sufficient to form a belief as to the truth of such allegations.

12. Bayer AG admits that Plaintiffs purport to commence an action seeking relief, but Bayer AG denies that Plaintiffs are entitled to any relief. Bayer AG admits that Baycol® is a prescription medication also known as cerivastatin sodium, and that cerivastatin sodium is known as Lipobay® in certain countries outside of the United States. Bayer AG denies that Plaintiffs were injured as a result of ingestion of Baycol® as sold by Bayer Corporation. Bayer AG is without knowledge or information sufficient to form a belief as to the truth of the remaining allegations in paragraph 12.

13. Bayer AG denies that it promoted and/or sold Baycol® in the United States.

Bayer AG admits that, prior to August 8, 2001, Bayer Corporation promoted and sold Baycol® in the United States, that prior to August 8, 2001, SmithKline Beecham Corporation d/b/a GlaxoSmithKline participated in the promotion of Baycol® in the United States, and that it is estimated that, prior to August 8, 2001, more than 700,000 persons took Baycol® in the United States. Because of the vagueness and ambiguity of the remaining allegations in paragraph 13, Bayer AG is without knowledge or information sufficient to form a belief as to the truth of such allegations.

14. Bayer AG denies the allegations in paragraph 14.
15. Bayer AG denies the allegations in paragraph 15.
16. Bayer AG denies the allegations in paragraph 16.
17. Bayer AG denies the allegations in paragraph 17.
18. Bayer AG admits that, prior to August 8, 2001, Bayer Corporation marketed Baycol® in the United States as safe for use in accordance with prescribing information and under the care of a physician or other health care provider. Bayer AG denies the remaining allegations in paragraph 18.
19. Bayer AG denies the allegations in paragraph 19.
20. Bayer AG denies the allegations in paragraph 20.
21. Bayer AG denies the allegations in paragraph 21.
22. Bayer AG denies the allegations in paragraph 22 to the extent that they relate to Bayer AG. Bayer AG admits that, prior to August 8, 2001, Bayer Corporation promoted, marketed, distributed and sold Baycol®, a prescription medication, in the United States, including in New York, and that prior to August 8, 2001, SmithKline Beecham Corporation d/b/a

GlaxoSmithKline participated in the promotion of Baycol® in the United States. Bayer AG admits that Bayer Corporation has promoted, marketed, distributed and/or sold certain prescription and non-prescription drug products in New York. Bayer AG denies that Bayer Corporation and SmithKline Beecham d/b/a GlaxoSmithKline manufactured Baycol®. Because of the vagueness and ambiguity of the remaining allegations in paragraph 22, Bayer AG is without knowledge or information sufficient to form a belief as to the truth of such allegations.

23. Bayer AG is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 23.

24. Bayer AG denies the allegations in paragraph 24.

25. Bayer AG admits that at least five other statins have been approved by the United States Food and Drug Administration (the “FDA”) for sale in the United States, and that statins block the activity of an enzyme that is involved in the production of cholesterol in the liver. Bayer AG is without knowledge or information sufficient to form a belief regarding the truth of the remaining allegations in paragraph 25.

26. Bayer AG denies the allegations in paragraph 26.

27. Bayer AG denies the allegations in paragraph 27.

28. Bayer AG denies the allegations in paragraph 28.

29. Bayer AG admits that in June 1997, the FDA approved Bayer Corporation’s application to market Baycol® in the United States, that prior to August 8, 2001, Bayer Corporation marketed Baycol® in the United States, and that prior to August 8, 2001, SmithKline Beecham Corporation d/b/a GlaxoSmithKline participated in the promotion of Baycol® in the United States. Bayer AG admits that Bayer Corporation voluntarily withdrew

Baycol® from the market in the United States on August 8, 2001. Bayer AG denies the remaining allegations in paragraph 29.

30. Bayer AG admits that the FDA made an announcement regarding the voluntary withdrawal of Baycol® from the market in the United States. That announcement is in writing and speaks for itself. To the extent that Plaintiffs' allegations regarding the content of that announcement are inconsistent with the actual language of the announcement, Bayer AG denies those allegations. Because of the vagueness and ambiguity of the remaining allegations in paragraph 30, Bayer AG is without knowledge or information sufficient to form a belief as to the truth of such allegations.

31. Because of the vagueness and ambiguity of the allegations in paragraph 31, Bayer AG is without knowledge or information sufficient to form a belief as to the truth of such allegations.

32. Bayer AG denies the allegations in paragraph 32.

33. Bayer AG admits that Bayer Corporation discontinued sampling of the 0.8 mg dose of Baycol® through Bayer Corporation's sales representatives in 2001. Bayer AG denies the remaining allegations in paragraph 33.

34. Paragraph 34 apparently purports to describe the FDA's announcement regarding Bayer Corporation's voluntary withdrawal of Baycol® from the market in the United States on August 8, 2001, which announcement is in writing and speaks for itself. To the extent that Plaintiffs' allegations regarding the content of that announcement are inconsistent with the actual language of the announcement, Bayer AG denies those allegations. Because of the vagueness and ambiguity of the remaining allegations in paragraph 34, Bayer AG is without knowledge or

information sufficient to form a belief as to the truth of such allegations.

35. Bayer AG denies the allegations in paragraph 35.
36. Because of the vagueness and ambiguity of the allegations in paragraph 36, Bayer AG is without knowledge or information sufficient to form a belief as to the truth of such allegations.
 37. Bayer AG denies the allegations in paragraph 37.
 38. Bayer AG denies the allegations in paragraph 38.
 39. Bayer AG denies the allegations in paragraph 39.
 40. Bayer AG denies the allegations in paragraph 40.
 41. Bayer AG denies the allegations in paragraph 41.
 42. Bayer AG denies the allegations in paragraph 42.
 43. Bayer AG denies the allegations in paragraph 43.
 44. Bayer AG denies the allegations in paragraph 44.
 45. Bayer AG denies the allegations in paragraph 45, except that Bayer AG admits that Baycol® as sold by Bayer Corporation was safe for use according to prescribing information and under the care of a physician or other health care provider.
46. Bayer AG denies the allegations in paragraph 46.
47. The February 18, 1998 announcement referred to in paragraph 47 is in writing and speaks for itself. To the extent that Plaintiffs' allegations regarding the content of that announcement are inconsistent with the actual language of the announcement, Bayer AG denies those allegations. Because of the vagueness and ambiguity of the remaining allegations in paragraph 47, Bayer AG is without knowledge or information sufficient to form a belief as to the

truth of such allegations.

48. Bayer AG admits that the FDA approved Bayer Corporation's application to market a 0.4 mg dose of Baycol® in the United States in May 1999. Bayer AG denies the remaining allegations in paragraph 48.

49. Because of the vagueness and ambiguity of the allegations in paragraph 49, Bayer AG is without knowledge or information sufficient to form a belief as to the truth of such allegations.

50. Bayer AG admits that paragraph 50 purports to describe an October 25, 1999 letter from Michael A. Misocky of the FDA's Division of Drug Marketing, Advertising and Communications to Bayer Corporation and certain written materials referred to in that letter. Those documents, being in writing, speak for themselves. To the extent that Plaintiffs' allegations regarding the contents of those documents are inconsistent with the actual language of the documents, Bayer AG denies those allegations. Bayer AG denies the remaining allegations in paragraph 50.

51. Because of the vagueness and ambiguity of the allegations in paragraph 51, Bayer AG is without knowledge or information sufficient to form a belief as to the truth of such allegations.

52. Bayer AG admits that the FDA approved Bayer Corporation's application to market a 0.8 mg dose of Baycol® in the United States in July 2000. Bayer AG denies the remaining allegations in paragraph 52.

53. Bayer AG admits that Bayer Corporation issued a "Dear Health Care Professional" letter in May 2001. That letter, being in writing, speaks for itself. To the extent

that Plaintiffs' allegations regarding the content of that letter are inconsistent with the actual language of the letter, Bayer AG denies those allegations. Bayer AG denies the remaining allegations in paragraph 53.

54. Bayer AG admits that, on August 8, 2001, Bayer Corporation voluntarily withdrew Baycol® from the market in the United States. Bayer AG denies the remaining allegations in paragraph 54.

55. Bayer AG denies the allegations in paragraph 55.

56. Bayer AG denies the allegations in paragraph 56.

57. Bayer AG denies the allegations in paragraph 57.

58. Bayer AG admits that, prior to August 8, 2001, SmithKline Beecham Corporation d/b/a GlaxoSmithKline participated in the promotion of Baycol® in the United States. Because of the vagueness and ambiguity of the remaining allegations in paragraph 58, Bayer AG is without knowledge or information sufficient to form a belief as to the truth of such allegations.

59. Bayer AG admits that, prior to August 8, 2001, Bayer Corporation promoted, marketed and distributed Baycol® in the United States. Because of the vagueness and ambiguity of the remaining allegations in paragraph 59, Bayer AG is without knowledge or information sufficient to form a belief as to the truth of such allegations.

60. Bayer AG is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 60.

61. Bayer AG is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 61.

62. In response to the allegations in paragraph 62, Bayer AG incorporates by

reference its responses to paragraphs 1 through 61 of the Complaint.

63. Bayer AG denies the allegations in paragraph 63.

64. Paragraph 64 sets forth conclusions of law to which no response is required. To the extent that a response is required, Bayer AG denies the allegations in paragraph 64.

65. Paragraph 65 sets forth conclusions of law to which no response is required. To the extent that a response is required, Bayer AG denies the allegations in paragraph 65.

66. Paragraph 66 sets forth conclusions of law to which no response is required. To the extent that a response is required, Bayer AG denies the allegations in paragraph 66.

COUNT I

67. In response to the allegations in paragraph 67, Bayer AG incorporates by reference its responses to paragraphs 1 through 66 of the Complaint.

68. Bayer AG denies the allegations in paragraph 68.

69. Bayer AG denies the allegations in paragraph 69.

70. Bayer AG denies the allegations in paragraph 70.

71. Bayer AG denies the allegations in paragraph 71, including subparts (a) through (i).

72. Bayer AG denies the allegations in paragraph 72.

73. Paragraph 73 sets forth conclusions of law to which no response is required. To the extent that a response is required, Bayer AG denies the allegations in paragraph 73.

74. Paragraph 74 sets forth conclusions of law to which no response is required. To the extent that a response is required, Bayer AG denies the allegations in paragraph 74.

75. Bayer AG denies the allegations in paragraph 75.

COUNT II

76. In response to the allegations in the first sentence in paragraph 76, Bayer AG incorporates by reference its responses to paragraphs 1 through 75 of the Complaint. Bayer AG denies the remaining allegations in paragraph 76.

77. Bayer AG denies the allegations in paragraph 77, including subparts (a) through (l).

78. Bayer AG denies the allegations in paragraph 78.

79. Bayer AG denies the allegations in paragraph 79.

80. Bayer AG denies the allegations in paragraph 80.

81. Bayer AG denies the allegations in paragraph 81.

82. Bayer AG denies the allegations in paragraph 82.

83. Paragraph 83 sets forth conclusions of law to which no response is required. To the extent that a response is required, Bayer AG denies the allegations in paragraph 83.

84. Bayer AG denies the allegations in paragraph 84.

COUNT III

85. In response to the allegations in paragraph 85, Bayer AG incorporates by reference its responses to paragraphs 1 through 84 of the Complaint.

86. Bayer AG admits that, prior to August 8, 2001, Bayer AG manufactured and sold cerivastatin sodium. Bayer AG also admits that, prior to August 8, 2001, Bayer Corporation marketed, promoted, distributed and sold Baycol® in the United States. Bayer AG further admits that, prior to August 8, 2001, SmithKline Beecham Corporation d/b/a GlaxoSmithKline participated in the promotion of Baycol® in the United States. Bayer AG denies that Bayer

Corporation, GlaxoSmithKline plc and SmithKline Beecham Corporation d/b/a GlaxoSmithKline manufactured Baycol®. Because of the vagueness and ambiguity of the remaining allegations in the first sentence in paragraph 86, Bayer AG is without knowledge or information sufficient to form a belief as to the truth of such allegations. Bayer AG denies the remaining allegations in paragraph 86, including subparts (a) through (g).

87. Bayer AG denies the allegations in paragraph 87.

88. Bayer AG denies the allegations in paragraph 88.

89. Bayer AG denies the allegations in paragraph 89.

90. Paragraph 90 sets forth conclusions of law to which no response is required. To the extent that a response is required, Bayer AG admits that, prior to August 8, 2001, Bayer AG manufactured cerivastatin sodium, and that, prior to August 8, 2001, Bayer Corporation sold Baycol® in the United States. Bayer AG denies that it violated any duty relating to Baycol® or the manufacture and/or sale of Baycol®, as alleged in the Complaint. Because of the vagueness and ambiguity of the remaining allegations in paragraph 90, Bayer AG is without knowledge or information sufficient to form a belief as to the truth of such allegations, including the allegation that Bayer AG had any duty to Plaintiffs.

91. Because of the vagueness and ambiguity of the allegations in paragraph 91, Bayer AG is without knowledge or information sufficient to form a belief as to the truth of such allegations.

92. Paragraph 92 sets forth conclusions of law to which no response is required. To the extent that a response is required, Bayer AG denies that it violated any duty relating to Baycol®, as alleged in the Complaint. Because of the vagueness and ambiguity of the remaining

allegations in paragraph 92, Bayer AG is without knowledge or information sufficient to form a belief as to the truth of such allegations, including any allegation that Bayer AG had any duty to Plaintiffs.

93. Bayer AG denies the allegations in paragraph 93, including subparts (a) through (d).

94. Bayer AG denies the allegations in paragraph 94.

95. Paragraph 95 sets forth conclusions of law to which no response is required. To the extent that a response is required, Bayer AG denies the allegations in paragraph 95.

96. Bayer AG denies the allegations in paragraph 96.

COUNT IV

97. In response to the allegations in paragraph 97, Bayer AG incorporates by reference its responses to paragraphs 1 through 96 of the Complaint.

98. Bayer AG denies the allegations in paragraph 98.

99. Bayer AG denies the allegations in paragraph 99.

100. Bayer AG denies the allegations in paragraph 100.

101. Bayer AG denies the allegations in paragraph 101.

102. Paragraph 102 sets forth conclusions of law to which no response is required. To the extent that a response is required, Bayer AG denies the allegations in paragraph 102.

103. Bayer AG denies the allegations in paragraph 103.

COUNT V

104. In response to the allegations in paragraph 104, Bayer AG incorporates by reference its responses to paragraphs 1 through 103 of the Complaint.

105. Paragraph 105 sets forth conclusions of law to which no response is required. To the extent that a response is required, Bayer AG admits that Baycol® was intended to be used to lower elevated plasma levels of total and low-density lipoprotein cholesterol and triglycerides, and to increase plasma levels of high-density lipoprotein cholesterol, in patients, and that, prior to August 8, 2001, Bayer Corporation marketed, sold, distributed and promoted Baycol® in the United States as safe for such use, according to prescribing information and under the care of a physician or other health care provider. Bayer AG denies the remaining allegations in paragraph 105.

106. Bayer AG denies the allegations in paragraph 106.

107. Bayer AG denies the allegations in paragraph 107.

108. Bayer AG denies the allegations in paragraph 108.

109. Bayer AG denies the allegations in paragraph 109.

110. Paragraph 110 sets forth conclusions of law to which no response is required. To the extent that a response is required, Bayer AG denies the allegations in paragraph 110.

111. Bayer AG denies the allegations in paragraph 111.

COUNT VI

112. In response to the allegations in paragraph 112, Bayer AG incorporates by reference its responses to paragraphs 1 through 111 of the Complaint.

113. Paragraph 113 sets forth conclusions of law to which no response is required. To the extent that a response is required, Bayer AG admits that, prior to August 8, 2001, Bayer Corporation marketed Baycol® in the United States as safe for use in accordance with prescribing information and under the care of a physician or other health care provider. Bayer

AG denies the remaining allegations in paragraph 113.

114. Bayer AG denies the allegations in paragraph 114.

115. Paragraph 115 sets forth conclusions of law to which no response is required. To the extent that a response is required, Bayer AG denies the allegations in paragraph 115.

116. Bayer AG denies the allegations in paragraph 116.

COUNT VII

117. In response to the allegations in paragraph 117, Bayer AG incorporates by reference its responses to paragraphs 1 through 116 of the Complaint.

118. Paragraph 118 sets forth conclusions of law to which no response is required. To the extent that a response is required, Bayer AG denies that it violated any law relating to Baycol®. Because of the vagueness and ambiguity of the remaining allegations in paragraph 118, Bayer AG is without knowledge or information sufficient to form a belief as to the truth of such allegations, including any allegation that Bayer AG had any obligation to Plaintiffs.

119. Paragraph 119 sets forth conclusions of law to which no response is required. To the extent that a response is required, Bayer AG denies the allegations in paragraph 119.

120. Bayer AG denies the allegations in paragraph 120.

121. Bayer AG denies the allegations in paragraph 121.

122. Bayer AG denies the allegations in paragraph 122.

123. Paragraph 123 sets forth conclusions of law to which no response is required. To the extent that a response is required, Bayer AG denies the allegations in paragraph 123.

124. Bayer AG denies the allegations in paragraph 124.

COUNT VIII

125. In response to the allegations in paragraph 125, Bayer AG incorporates by reference its responses to paragraphs 1 through 124 of the Complaint.

126. Bayer AG denies the allegations in paragraph 126.

127. Bayer AG admits that it was aware of potential risks associated with Baycol® and that Baycol® as sold by Bayer Corporation was accompanied by adequate warnings regarding the potential risks associated with Baycol®. The labeling for Baycol® is in writing and speaks for itself. To the extent that Plaintiffs' allegations regarding that labeling are inconsistent with the actual language of the labeling, Bayer AG denies those allegations. Bayer AG is without knowledge or information sufficient to form a belief as to the truth of the allegation that Plaintiffs were intended users of Baycol®. Bayer AG denies the remaining allegations in paragraph 127.

128. Bayer AG denies the allegations in paragraph 128.

129. Bayer AG denies the allegations in paragraph 129.

130. Paragraph 130 sets forth conclusions of law to which no response is required. To the extent that a response is required, Bayer AG denies the allegations in paragraph 130.

131. Bayer AG denies the allegations in paragraph 131.

COUNT IX

132. In response to the allegations in paragraph 132, Bayer AG incorporates by reference its responses to paragraphs 1 through 131 of the Complaint.

133. Bayer AG is without knowledge or information sufficient to form a belief as to

the truth of the allegations in paragraph 133.

134. Bayer AG denies the allegations in paragraph 134.

135. Paragraph 135 sets forth conclusions of law to which no response is required. To the extent that a response is required, Bayer AG denies the allegations in paragraph 135.

136. Bayer AG denies the allegations in paragraph 136.

137. Bayer AG denies the allegations in the Prayer for Relief. Bayer AG denies that Plaintiffs are entitled to any relief whatsoever.

138. Bayer AG denies all allegations in the Complaint that relate or are directed to Bayer AG unless those allegations are expressly admitted in this Answer.

ADDITIONAL DEFENSES

1. Plaintiffs' Complaint, and each and every count contained therein, fails to state a cause of action or claim upon which relief can be granted against Bayer AG.

2. Some or all of Plaintiffs' claims are barred by the applicable statutes of limitations and/or statutes of repose.

3. Plaintiffs' claims against Bayer AG are barred, in whole or in part, by laches, waiver and/or estoppel.

4. Plaintiffs' claims are barred, in whole or in part, by Plaintiffs' failure to mitigate alleged damages.

5. If Plaintiffs sustained the injuries or incurred the expenses as alleged, which is expressly denied, said injuries or expenses were directly and proximately caused by the negligence or fault of parties other than Bayer AG, whether named or unnamed in Plaintiffs' Complaint, over whom Bayer AG had no supervision or control and for whose actions and

omissions Bayer AG has no legal responsibility. Plaintiffs' recovery, if any, therefore should be apportioned in accordance with the applicable law.

6. The injuries and damages claimed by Plaintiffs, if any, resulted from an intervening or superseding cause and/or causes, and any act or omission on the part of Bayer AG was not the proximate and/or competent producing cause of such alleged injuries and damages.

7. If Plaintiffs suffered injuries as alleged in the Complaint, which is expressly denied, such injuries arose from, and were caused by, risks, hazards, and dangers knowingly assumed by Plaintiffs. Plaintiffs' recovery accordingly is barred or should be reduced by Plaintiffs' assumption of the risk.

8. Baycol® is a prescription pharmaceutical which was available only upon the prescription of a licensed physician. The claims in the Complaint against Bayer AG accordingly are barred in whole or in part by the learned intermediary doctrine.

9. Plaintiffs' recovery is barred and/or should be reduced under the applicable law because of Plaintiffs' contributory negligence or fault and/or comparative negligence or fault.

10. Plaintiffs' Complaint fails to state a claim upon which relief can be granted against Bayer AG in that the methods, standards, and techniques utilized with respect to the design, manufacture, marketing and sale of the prescription drug Baycol®, including adequate warnings and instructions with respect to the product's use included in the product's package insert and other literature, conformed to the applicable state of the art, and the product was designed, manufactured, marketed and sold in a reasonable and prudent manner based upon available medical and scientific knowledge.

11. Plaintiffs' claims are barred as a matter of law pursuant to Restatement (Second) of Torts § 402A, comment k.

12. The prescription drug Baycol® complied with the applicable product safety regulations promulgated by the FDA. Compliance with such regulations demonstrates that due care was exercised with respect to the design, manufacture, testing, marketing and sale of this prescription drug, and that it was neither defective nor unreasonably dangerous.

13. Plaintiffs' claims are preempted, in whole or in part, by federal law pursuant to the Supremacy Clause of the United States Constitution because of the federal regulation of prescription drug manufacturing, testing, marketing, and labeling.

14. If Plaintiffs sustained the injuries or incurred the expenses as alleged, which is expressly denied, said injuries or expenses were caused by the unforeseeable alteration, improper handling, or other unforeseeable misuse of the prescription drug Baycol®.

15. Any claims by Plaintiffs relating to alleged communications with regulatory agencies of the United States government are barred in whole or in part by operation of applicable law, including First Amendment rights to petition the government.

16. The alleged injuries and damages, if any, were the result of unavoidable circumstances that could not have been prevented by any person, including Bayer AG.

17. Plaintiffs' Complaint fails to state a claim against Bayer AG upon which relief can be granted for several or joint and several liability.

18. Plaintiffs' Complaint fails to join indispensable parties necessary for the just adjudication of this matter.

19. Plaintiffs' Complaint fails to state a claim against Bayer AG upon which relief can be granted as to costs, expenses, attorneys' fees, pre-judgment interest and post-judgment interest.

20. Plaintiffs' claims are barred in whole or in part because the commercial speech relating to Baycol® was not false or misleading and is protected under the First Amendment of the United States Constitution and the applicable state constitution.

21. Plaintiffs' claims regarding warnings and labeling are barred in whole or in part by the doctrine of primary jurisdiction, in that the FDA is charged under law with determining the content of warnings and labeling for prescription drugs.

22. Plaintiffs cannot state a claim with regard to warnings and labeling for prescription drugs because the remedy sought by Plaintiffs is subject to the exclusive regulation of the FDA.

23. This court should abstain from adjudicating Plaintiffs' claims relating to warnings and labeling in deference to the interpretation of regulations relating to prescription drug labeling by the FDA.

24. Upon information and belief, each item of economic loss alleged in the Complaint was, or with reasonable certainty will be, replaced or indemnified in whole or in part by collateral sources.

25. Plaintiffs did not detrimentally rely on any labeling, warnings or information concerning Baycol®.

26. Plaintiffs' alleged injuries and damages, if any, were the result of an idiosyncratic reaction, which Bayer AG could not reasonably foresee.

27. Plaintiffs' claims for breach of warranty are barred because Plaintiffs failed to give timely notice of any alleged breach of warranty.

28. Bayer AG did not sell or distribute the prescription drug Baycol® directly to Plaintiffs, and Plaintiffs did not receive or rely upon any representations or warranties as alleged in the Complaint. Plaintiffs' claims are barred by lack of privity between Plaintiffs and Bayer AG.

29. Plaintiffs' claims for breach of warranty, express or implied, are barred by the applicable provisions of the Uniform Commercial Code.

30. Plaintiffs' Complaint fails to state a claim upon which relief can be granted under the Magnuson-Moss Act.

31. Plaintiffs' purported allegations of fraud, deceit, misrepresentation and concealment do not comply with Rule 9(b) of the Federal Rules of Civil Procedure.

32. Plaintiffs' Complaint fails to state a claim for fraud, deceit, misrepresentation and/or concealment.

33. Plaintiffs' Complaint fails to state a claim against Bayer AG upon which relief can be granted for punitive or exemplary damages.

34. Plaintiffs' claims for punitive or exemplary damages are barred under the applicable state and federal law. Permitting recovery of punitive or exemplary damages in this case would contravene Bayer AG's constitutional rights as reserved by the Fifth, Seventh, Eighth, and Fourteenth Amendments to the United States Constitution and other provisions of the United States Constitution and the applicable state constitution.

35. Because of the lack of clear standards, the imposition of punitive or exemplary damages against Bayer AG would be unconstitutionally vague and/or overbroad.

36. With respect to Plaintiffs' demand for punitive or exemplary damages, Bayer AG specifically incorporates by reference any and all standards or limitations regarding the determination and enforceability of punitive or exemplary damages awards under the applicable state law.

37. No act or omission of Bayer AG was malicious, willful, wanton or with actual malice, and Plaintiffs' Complaint fails to state a claim upon which relief can be granted for punitive or exemplary damages. Plaintiffs' Complaint seeks damages in excess of those permitted by law. Bayer AG asserts any statutory or judicial protection from punitive or exemplary damages that is available under the applicable law, and any award of punitive or exemplary damages is barred.

38. Any award of punitive or exemplary damages against Bayer AG is barred to the extent that it is inconsistent with the standards and limitations set forth in *BMW of North America, Inc. v. Gore*, 517 U.S. 559 (1996), and *State Farm Mutual Automobile Insurance Co. v. Campbell*, 538 U.S. 408 (2003).

39. Plaintiffs' claims asserted under the United States Food Drug and Cosmetic Act, 21 U.S.C. §§ 301 et seq., and other statutes and regulations, fail because those statutes and regulations do not contain or create any private cause of action.

40. Plaintiffs' Complaint fails to state a claim upon which relief can be granted for negligence per se.

41. Under applicable state law, there exist no post-sale duties, including a post-sale duty to warn, in the present circumstances. Accordingly, Plaintiffs' Complaint fails to state a claim against Bayer AG upon which relief can be granted for alleged breach of post-sale duties, including allegedly inadequate post-sale marketing or alleged post-sale duty to warn.

42. Plaintiffs' Complaint fails to state a claim for unlawful conduct under New York's Consumer Protection From Deceptive Acts and Practices Act, General Business Law §§ 349 and 350, because Bayer AG completely complied with the applicable law in connection with the design, manufacture and sale of cerivastatin sodium.

43. Plaintiffs' Complaint fails to state a claim for misleading or unfair advertising or for deceptive business practices under New York's Consumer Protection From Deceptive Acts and Practices Act because no conduct of Bayer AG was misleading, unfair or deceptive.

44. Plaintiffs' claims are barred in whole or in part because New York's Consumer Protection From Deceptive Acts and Practices Act is insufficiently definite to provide adequate or fair notice of the conduct proscribed, in violation of the Due Process Clauses of the Fifth and Fourteenth Amendments to the United States Constitution and the due process protections of the applicable state constitution.

45. Plaintiffs' claims are barred in whole or in part because New York's Consumer Protection From Deceptive Acts and Practices Act unconstitutionally burdens interstate business practices relating to prescription drugs, which are heavily regulated by the FDA.

46. Plaintiffs' claims may be barred in whole or in part by release.

47. Whatever damages may have been sustained at the time and place alleged in the Complaint by Plaintiffs were caused, in whole or in part, by the culpable conduct of Plaintiffs

and without any negligence on the part of Bayer AG. Damages, if any, are to be diminished proportionately to the culpable conduct of Plaintiffs.

48. The equitable share of liability, if any, of Bayer AG shall be determined pursuant to the provisions of Article 16 of the New York State's Civil Practice Law and Rules.

49. Plaintiffs' claims have been improperly joined in this action.

50. Venue is improper.

51. This Court is not the proper forum and is not a convenient forum for the adjudication of Plaintiffs' claims.

52. Bayer AG adopts and incorporates by reference all defenses pleaded by other defendants except to the extent that they are inconsistent with Bayer AG's defenses pleaded in this Answer.

53. Bayer AG reserves the right to amend its Answer and separate and additional defenses to conform to such facts as may be revealed in discovery or otherwise.

WHEREFORE, Bayer AG prays that judgment be entered in its favor and against Plaintiffs, and that Bayer AG be awarded costs and such other and further relief as the Court deems just and appropriate.

JURY TRIAL DEMAND

Bayer AG demands a trial by jury on all issues so triable.

Dated: New York, New York
March 5, 2004

Respectfully yours,

HEIDELL, PITTONI, MURPHY & BACH, LLP

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